



STATE MEDICAID DUR BOARD MEETING
THURSDAY, June 13, 2013
7:00 a.m. to 8:30 a.m.
Cannon Health Building
Room 125



MINUTES

Board Members Present:

Jay Aldous, DDS
Mark Balk, PharmD.
Keith Tolman, M.D.
Cris Cowley, M.D.
Susan Siegfried, M.D.

Tony Dalpiaz, PharmD.
Jennifer Brinton, MD
Kathy Goodfellow, R.Ph.

Board Members Excused:

George Hamlin, PharmD
Bradford Hare, M.D.

Mr. Kumar Shah
Kyle Jones, M.D.

Dept. of Health/Div. of Health Care Financing Staff Present:

Tim Morley, R.Ph.
Bobbi Hansen, C.Ph.T.
Trevor Smith C.Ph.T.
Heather Santacruz, R.N.
Marisha Kissell, R.N.

Robyn Seely, PharmD.
Lisa V Hunt, R.Ph.
Richard Sorenson, R.N.
Merelynn Berrett, R.N.

Other Individuals Present:

Bryan Larson, UofU
Scott Turpin, UofU
Scott Larson, BMS
Sumar Bieda, Purdue

Kelsey Ricahrds, UofU
Joanita Lake, UofU
Lori Harwarth, Bayer

Meeting conducted by: Tony Dalpiaz, Pharm.D.

1. **Welcome** – Tony Dalpiaz opened the meeting.
2. **Housekeeping** – Robyn Seely reminded guests and board members to sign in.
3. **P&T Committee report** – Lisa Hunt addressed the board. She announced that a new Preferred Drug List was posted and effective June 1, 2013. P&T will not be meeting in June. In July they will be reviewing the sulfonylaurea drug class.
4. **Approval of prior meeting minutes** – Keith Tolman made a motion to approve the May minutes as written. Kathy Goodfellow seconded the motion. The motion was approved unanimously.

5. **Xifaxan (rifaximin)** – Joanita Lake presented the clinical evidence prepared by the University of Utah Drug Information Center.

Robyn Seely explained to the board members that they are looking at this medication today to see if there is a need to enforce on-label use. She also presented some purposed prior authorization criteria to the board:

- Traveler's Diarrhea:
 - Age \geq 12 years
 - For treatment, not for prophylaxis
 - Must reasonably be believed to be caused by *Escherichia coli* – please describe
 - Maximum 200mg three times daily for 3 days
- Overt Hepatic Encephalopathy
 - Age \geq 18 years
 - For prophylaxis of recurrence – please describe previous occurrences and therapies
 - Maximum 550mg twice daily

Mark Balk asked if there was additional information about the utilization for patients under 9 years old, given that the only indication for this age group is traveler's diarrhea. Historically Utah Medicaid has not required a diagnosis be submitted with this medication, therefore many of the claims that have been received did not contain a diagnosis code and so the indication for which it was prescribed is unknown from claims data alone.

Public Comment – No public comment.

Robyn Seely stated to the board that although Xifaxan is highly prescribed for irritable bowel syndrome (IBS), it is off label and the purpose of the prior authorization criteria is to encourage on-label use.

Susan Siegfried suggested that the criteria reflect the guideline that Xifaxan should only be used in patients to treat traveler's diarrhea that do not see an improvement on fluoroquinolones within 48 hours. Additionally, she suggested that the treatment of overt hepatic encephalopathy include a failure or contraindication to lactulose.

Keith Tolman stated that as a Gastroenterologist that treats irritable bowel syndrome, traveler's diarrhea, and hepatic encephalopathy, he has never prescribed Xifaxan. Joanita Lake stated that although Xifaxan is shown to be as effective as lactulose, it does not carry the same side effects (if not dosed or titrated correct lactulose can lead to diarrhea).

Keith Tolman made a statement "did you know what bug it was," in regards to those who have suffered from traveler's diarrhea. Xifaxan is specifically indicated to treat *Escherichia coli*. He stated that the most common is caused by *B. cereus* (*Bacillus cereus*), which last approximately 12 hours. Susan Siegfried stated that by the time the majority of patients reach their doctor they have had symptoms long enough that they have been exposed to some antibiotic, making a culture inaccurate at best. Susan suggested, that due

to the difficulty and time involved in properly diagnosing the cause of the diarrhea there are cost effective over-the-counter alternatives that can be used.

Cris Cowley asked about who was prescribing this medication and for which indications. The utilization data did not identify which prescriber specialty (or provider type) was tied to each of the diagnosis codes that were submitted. Additionally, not all the utilization data contained diagnosis codes.

Tony Dalpiaz asked if it was necessary to keep the criteria requirement that traveler's diarrhea "must reasonably be believed to be caused by *Escherichia coli*," given its difficulty to diagnosis. The board members agreed that this is important criteria to keep the coverage on-label only.

Keith Tolman asked if there were any patients that would be affected if this medication were just not available. Mark Balk stated that the DUR Board has never had the authority to not cover a drug, just whether it is covered with or without a prior authorization.

The board discussed if there was a need to add to the criteria any dosage adjustment criteria for different stages of hepatic encephalopathy. Mark Balk stated that the package insert indicates that Xifaxan can be used to treat mild or moderate hepatic encephalopathy; it does not specify any dose change in these instances and it was not studied in severe cases.

Board Action – Mark Balk made a motion that the criteria be accepted and re-reviewed in 9 months with the following additions:

- Traveler's Diarrhea:
 - Trial and failure of, or contraindication to, a fluoroquinolone or azithromycin.
- Overt Hepatic Encephalopathy
 - Trial and failure of, or contraindication to, properly doses and titrated lactulose.

Cris Cowley seconded the motion. The motion was approved unanimously.

6. **Meeting adjourned** – In the future when petitions are to be reviewed and the meeting is to be closed to the public a vote or motion to close the meeting is required (per the Public Open Meetings Act). No petitions to review so no vote is needed, meeting was adjourned.

The next DUR Board meeting is scheduled for Thursday, July 11, 2013.

Minutes prepared by Bobbi Hansen.

Recording available upon request, send email to medicaidpharmacy@utah.gov

No petitions were considered in June.